K122199

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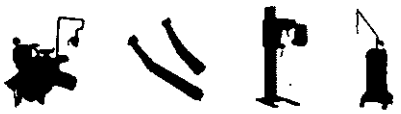

Section 6- 510(k) Summary

APR 18 2013

a. Owner/Company name, address

THE YOSHIDA DENTAL MFG. CO., LTD.
1-3-6, Kotobashi, Sumida-ku
Tokyo
130-8516, Japan

Michizo Yamanaka
President

- Contact person

Hidenori Watanabe
Regulatory Affairs
Phone: 011-81- 3-3631-2165
Fax: 011-81- 3-3633-9420
Email: hi-watanabe@yoshida-net.co.jp

b. Contact/Application Correspondent

Toshimitsu Murakami
General Manager, Product Development Dept.
PreXion Co., Ltd.
1-14-1 Kandasuda-cho,
Funai Tokyo Technology Center Building 10F,
Chiyoda-ku, Tokyo, 101-0041,
Japan

Phone: 011-81-3-5297-2822
Fax: 011-81-3-5297-7552
Email: toshim@prexion.co.jp

c. Date prepared

July 20, 2012

d. Name of device

Trade Name:	PREXION3D ECLIPSE
Common Name:	Computed tomography x-ray system
Classification Name:	X-ray, tomography, computed, dental
Classification Regulation:	21 CFR 892.1750

e. Predicate devices

The PREXION3D ECLIPSE is substantially equivalent to the following legally marketed device:

510(k) Number	Trade name	Product code
K063622	FINECUBE	OAS
K103659	CS 9300	OAS
K111231	PANOURA 18S	MUH

The predicate devices are hereinafter called "the FINECUBE (k063622)", "CS 9300 (K103659), or "the PANOURA 18S (k111231)" in this application.

f. Description of the device

The PREXION3D ECLIPSE consists of scanner and two software including Console software, and Viewer software used for the Image Analysis System and Data processing. A qualified computer named Console computer is distributed with the PREXION3D ECLIPSE.

The PREXION3D ECLIPSE uses the Image Analysis System and the processed data acquired by the scanner to analyze 2D and 3D images, perform image edition, such as creating cross-section views, and output results to a printer or other output device.

During scanning, X-rays are generated from the X-ray tube head mounted in the arm of the scanner and the X-rays passing through a patient are then detected by the flat panel detector of the scanner under the control of the firmware and the Console software installed on the qualified computer. The detected X-ray absorption data is processed by the Console software and viewer software on each computer to reconstruct images. Scanning is performed using X-ray penetration signals of a patient taken from multiple directions to produce two-dimensional and three-dimensional digital X-ray images of the dento-maxillo-facial region for the diagnosis of hard tissue
The PREXION3D ECLIPSE performs three types of scanning including CT scan generating two (2) or three (3) dimensional images, Panoramic scan generating two (2) dimensional images and Cephalometric radiography generating a plain radiographic image.

g. Indications for Use

PREXION3D ECLIPSE is intended to produce two-dimensional digital panoramic and cephalometric images, and three-dimensional digital X-ray images of the dento-maxillo-facial region at the direction of healthcare professionals as diagnostic support.

h. Statement of substantial equivalence

The PREXION3D ECLIPSE was developed from the FINECUBE (k063622) by adding panoramic scan function and cephalometric radiography. Following characteristics of the PREXION3D ECLIPSE are identical or similar to those of the FINECUBE (k063622);

- X-ray Generation features including tube voltage, tube current, and focal Spot Size

- X-ray image capturing features for CT scan including type of detector, pixel size, and pixel number

The difference of the PREXION3D ECLIPSE from the FINECUBE (k063622) is addition of panoramic scanning function and cephalometric radiography.

The panoramic scanning function of the PREXION3D ECLIPSE is similar to that of CS 9300 (k103659). The PREXION3D ECLIPSE has the similar characteristics to CS 9300 (k103659) regarding X-ray generation features including tube voltage, tube current and focal spot size, X-ray image capturing features including type of detector and pixel numbers.
The intended use of the PREXION3D ECLIPSE is identical to part of intended use of the CS 9300 (k103659), and similar to the intended use of the FINECUBE (k063622).

The fundamental technology of cephalometric radiography of the PREXION3D ECLIPSE is identical to that of the PANOURA 18S (k111231). The PREXION3D ECLIPSE has the similar characteristic regarding X-ray generation features including tube voltage, tube current and focal spot size. The X-ray image capturing device of the PREXION3D ECLIPSE is different from that of the PANOURA 18S (k111231).

In order to ensure same performance characteristics as predicate devices, software validation, performance testing, and risk analysis were performed. Such test results and risk analysis indicate that the PREXION3D ECLIPSE meets the requirements of the recognized consensus or voluntary standard. Based on the information presented above we conclude that the PREXION3D ECLIPSE is substantially equivalent to the predicate devices and does not raise any new questions regarding safety or effectiveness.

i. Comparison table

Table 6-1 compares the characteristics between the PREXION3D ECLIPSE and the predicates.

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Table 6-1. Comparison Table

Item		PREXION3D ECLIPSE	FINECUBE (k063622)	CS 9300 (k103659)	PANOURA 18S(k111231)
Indications for Use		PREXION3D ECLIPSE is intended to produce two-dimensional digital panoramic and cephalometric images, and three-dimensional digital X-ray images of the dento-maxillo-facial region at the direction of healthcare professionals as diagnostic support.	FINECUBE is an x-ray device (cone beam computed tomography) that acquires a single 360 degree rotational sequence of the head and neck areas, including the ENT and dentomaxillofacial area for use in diagnostic support. The device is operated and used by physicians, dentists, and x-ray technologists.	The CS 9300 and CS 9300C are systems intended to produce two-dimensional and three-dimensional digital x-ray images of the dento-maxillo-facial, and ENT (Ear, Nose and Throat) regions at the direction of healthcare professionals as diagnostic support for pediatric and adult patients. In addition, the CS 9300C is intended to produce cephalometric images. This includes imaging the hand and. wrist to obtain the carpus image for growth and maturity assessment.	The Panoura 18S dental panoramic and cephalometric device is intended for dental radiographic examinations of teeth, jaw and TMJ areas by producing conventional 2D X-ray images as well as X-ray projection images. The device must only be operated and used by dentists and other legally qualified professionals.
X ray Generation Device	Tube Voltage	50 - 90kV	90kV	60 - 90kV	58 - 82kV
	Tube Current	1 - 4mA	4mA	2 - 15mA	2.0 - 10mA
	Focal Spot Size	0.2mm	0.2mm	0.7mm	0.5mm
X ray image capturing device	Detector	FPD	FPD	FPD (TFT)	CMOS
	Pixel size	200μm (CT) 100μm (Panoramic) 54μm (Ceph)	200μm	-	100 x 100 μm
	Pixel number	640 x 656 (CT) 80 x 1312 (Panoramic) 128 x4080 (Ceph)	608 x 616	64 x 1536 (Panoramic)	64 x 1536 (Panoramic) 64 x 2266 (Ceph)

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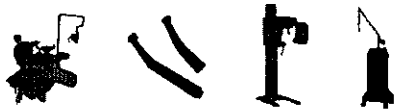

Item		PREXION3D ECLIPSE	FINECUBE (k063622)	CS 9300 (k103659)	PANOURA 18S(k111231)
	Size of Area receiving X-ray.	128.1mm x 131.3mm (CT) 8mm x 131.3mm (Panoramic) 6.9mm x 312mm (Ceph)	121.6mm x 123.2mm	5 x 149 mm max (Panoramic)	5 mm x 149 mm max (Panoramic) 6.4mm x 226.6mm (Ceph)
	Number of Bit	14bits (CT, Panoramic) 16bits (Ceph)	12bits	14 bits	14 bits
Scanner	SID/SOD	620 mm / 400 mm (CT, Panoramic) 1650 mm / 1500 mm (Ceph)	700mm/322mm(Magnification imaging) 700mm/468mm(Wide area imaging)	615mm (SID)	615mm (Panoramic) 1650 mm / 1500 mm (Ceph)
	Dimension (W×D×H)	1245mm×1288mm×2045mm (CT, pan) 1805mm×1288mm×2045mm (Ceph)	1170mm×1530mm×1930mm	1158mm×1595mm×2378mm	1158mm×1595mm×2378mm (Pan) 1835mm x1192mm x 2378mm (Ceph)
	Weight	260kg (CT, Pan) 300kg(Ceph)	390kg	160kg (CT, Panorama) 190Kg (Ceph)	160kg (Panoramic) 215kg (Ceph)
Imaging mode		CT scan, Panoramic scan, Cephalometric radiography	CT Scan	CT Scan, Panoramic Scan, Cephalometric radiography	Panoramic Scan, Cephalometric radiography
Panoramic scan Performance	Scan time	Standard mode: 16 sec	-	4 - 16 sec	4 - 16 sec
Cephalometric radiography	Scan time	LA, PA, Carpus: 8, 10, 12, 15sec	-	0.1-3.2 sec	LA, PA, Carpus: 8, 10 sec
CT scan Performance	Scan time	Light mode: 8.7sec High Definition mode: 8.7 sec Ultra High Definition mode: 17.4 sec Wide mode: 9.1 sec x 2	19sec. (Standard mode) 37sec. (High density mode)	12 - 20 sec 28 sec	-
	FOV (voxel size)	Light mode, High Definition mode, Ultra High Definition mode: Diameter 81 mm, H 75mm	Wide area imaging φ82.0mm H75.1mm	φ170mm/H135mm (0.090mm - 0.500mm)	-

Item		PREXION3D ECLIPSE	FINECUBE (k063622)	CS 9300 (k103659)	PANOURA 18S(k111231)
			Magnification imaging φ56.5mm, H51.7mm	φ170mm/H110mm (0.090mm - 0.500mm)	-
		Wide mode: Diameter 113mm, H 72mm	-	φ170mm/H60mm (0.090mm - 0.500mm)	-
			-	φ100mm/H100mm (0.090mm - 0.500mm)	-
			-	φ80mm/H80mm (0.090mm - 0.500mm)	-
			-	φ100mm/H50mm (0.090mm - 0.500mm)	-
				φ50mm/H50mm (0.090mm - 0.500mm)	-

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j. Risk Analysis

The PREXION3D ECLIPSE was evaluated in accordance with ISO14971:2007. The risk management of the device was deemed satisfactory.

k. Bench Testing

THE YOSHIDA DENTAL MFG. CO., LTD has performed bench tests to ensure safety and effectiveness as follows;

1. Laser Safety

The laser system of the PREXION3D ECLIPSE is identical to that of the PANOURA 18S (K111231). Therefore, the test report for IEC 60825-1 for the PANOURA 18S (K111231) is used as the test report for the PREXION3D ECLIPSE.

2. Modulation-Transfer Function

In order to evaluate the spatial resolution of the PREXION3D ECLIPSE, we measured the MTF in accordance with IEC 61223-3-5. The spatial resolution of all scan modes met the acceptance criteria.

3. Artifact Analysis

In order to evaluate the artifact of the image of the PREXION3D ECLIPSE, the images of all scan mode of the PREXION3D ECLIPSE were compared to those of the FINECUBE (K063622). There was no difference of pattern and strength of the metal artifact between the PREXION3D ECLIPSE and the FINECUBE(K063622).

The software of the PREXION3D ECLIPSE has been validated according to "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

EMC, Electric safety, and X-ray radiation safety are confirmed in accordance with IEC60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-2-7, IEC 60601-2-28, and IEC 60601-2-32.

l. Conclusion

The PREXION3D ECLIPSE has similar intended use and technical characteristics to the predicate devices including the FINECUBE (k063622), CS 9300 (k103659), and the PANOURA 18S (K111231). A number of test results and risk analysis indicate that the PREXION3D ECLIPSE meets the requirements of the recognized consensus or voluntary standard. Based on those information, we conclude that the PREXION3D ECLIPSE is substantially equivalent to the predicate devices and does not raise any new questions regarding safety or effectiveness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 18, 2013

The Yoshida Dental Mfg. Co., LTD.
% Mr. Toshimitsu Murakami
General Manager, Product Development Dept.
PreXion Co., Ltd.
1-14-1 Kandasuda-cho
Funai Tokyo Technology Center Building 10F
Chiyoda-ku, Tokyo, 101-0041
JAPAN

Re: K122199
Trade Name: PreXion 3D Eclipse
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: II
Product Code: OAS
Dated: March 29, 2013
Received: April 3, 2013

Dear Mr. Murakami:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122199

Device Name: PreXion 3D Eclipse

Indications for Use:

PREXION3D ECLIPSE is intended to produce two-dimensional digital panoramic and cephalometric images, and three-dimensional digital x-ray images of the dento-maxillo-facial region at the direction of healthcare professionals as diagnostic support.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

510(k) K122199